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APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/966,686	10/01/2001	Michael Austin	\$63.2-10142	1843	
490	7590 07/02/2002				
VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000			EXAMINER		
			JIMENEZ, MARC QUEMUEL		
MINNETONK	CA, MN 55343-9185		ART UNIT	PAPER NUMBER	
			3726	<u></u>	
			DATE MAILED: 07/02/2002		

Please find below and/or attached an Office communication concerning this application or proceeding.

<del>-</del>		Application No.		Applicant(s)				
		09/966,686	·	AUSTIN, MICHAEL				
Office Action Summary		Examiner		Art Unit				
		Marc Jimenez		3726				
<b></b>	The MAILING DATE of this communication appears on the cover sheet with the correspondence address							
	or Reply	/ IC CET TO EVE	NDE AMONTHU	C) EDOM				
THE - Extended after - If the second of the	HORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION.  The ensions of time may be available under the provisions of 37 CFR 1.13 or SIX (6) MONTHS from the mailing date of this communication.  The eperiod for reply specified above is less than thirty (30) days, a reply operiod for reply is specified above, the maximum statutory period we ure to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing led patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, howe within the statutory min will apply and will expire s cause the application to	ever, may a reply be tim imum of thirty (30) days SIX (6) MONTHS from b become ABANDONED	ely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133).				
Status								
1)🛛	Responsive to communication(s) filed on 24 h							
2a)⊠	,—	is action is non-fi		er en				
3)U	Since this application is in condition for allowal closed in accordance with the practice under a tion of Claims							
	Claim(s) 27-43 is/are pending in the applicatio	n.						
·	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)□								
6)⊠								
7)								
8)□	Claim(s) are subject to restriction and/or	r election require	ment.					
Applicat	ion Papers							
	The specification is objected to by the Examiner							
10)	The drawing(s) filed on is/are: a) accept							
	Applicant may not request that any objection to the							
11)[_]	The proposed drawing correction filed on			Ved by the Examiner.				
If approved, corrected drawings are required in reply to this Office action.  12)☐ The oath or declaration is objected to by the Examiner.								
,—	•	annen.						
	under 35 U.S.C. §§ 119 and 120	. maiority undor 25	:1166 \$ 440/5	) (d) or (f)				
•	13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a,	a) All b) Some * c) None of:							
	1. Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No							
* ;	<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
14) 🗌 /	14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
	a)  The translation of the foreign language pro Acknowledgment is made of a claim for domesti	• •						
Attachmer	nt(s)							
2) 🔲 Notic	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	4)		(PTO-413) Paper No(s) Patent Application (PTO-152)				

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#### **DETAILED ACTION**

### **Drawings**

1. The drawings filed 5/24/2002 should be re-filed as a separate paper with a transmittal letter addressed to the Official Draftsperson. (see 37 CFR 1.85).

# Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in-
- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).
- 3. Claims 27, 28, 33-36, and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Morales (5,893,852).

Morales teaches a method of reducing a stent in cross-section comprising the steps of:

4. providing a plurality of closely spaced wedge-shaped dies 30, the dies 30 disposed about a circle 66 (see fig. 5A) and forming an aperture, placing a stent 10 within the aperture (see fig. 2), and moving the dies 30 so as to reduce the size of the aperture and apply an inward force to the stent (col. 8, lines 60-64).

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Note that the stent 10 is disposed about a medical balloon 14, the medical balloon 14 disposed about a catheter 11, the stent 10 is deformed, and the dies 30 are moved cooperatively inward during the moving step.

5. Claims 27, 28, 33-36, and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Morales (6,167,605).

Morales teaches a method of reducing a stent 10 in cross section comprising the steps of providing a plurality of closely spaced wedge-shaped dies 30, the dies 30 disposed about a circle and forming an aperture 58, placing a stent 10 within the aperture 58, moving the dies 30 so as to reduce the size of the aperture 58 and apply an inward force to the stent 10.

Note that the stent 10 is disposed about a medical balloon 14, the medical balloon 14 disposed about a catheter 11, the stent 10 is deformed, and the dies 30 are moved cooperatively inward during the moving step.

# Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 31, 32, 39, and 40 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Morales (5,893,852).

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Although Morales teaches that the number of wedge-shaped dies 30 can be more than four teeth (col. 9, line 24), this teaching suggest that the number of wedge-shaped dies covers 8 or 16 dies since a number more than 4 covers 8 and 16, Morales does not specifically teach having either 8 wedge-shaped dies or 16 wedge-shaped dies.

It would have been obvious to one of ordinary skill in the art, at the time of the invention, that the particular number of wedge-shaped dies is clearly a matter of design choice, wherein no significant problems are solved by using either 8 or 16 wedge-shaped dies, versus using 4 or more wedge shaped dies as taught by Morales. It appears that using 4 or more wedge-shaped dies as taught by Morales would work equally as well as using the claimed 8 or 16 wedge-shaped dies.

8. Claims 29 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (5,893,852) in view of Charzewski (4,942,756).

Morales teaches the invention cited above with the exception of changing the temperature of the dies or cooling the dies.

Charzewski teaches dies 1a-c that have a temperature change (col. 4, lines 3-9).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of Morales with dies having a temperature change, in light of the teachings of Charzewski, in order to facilitate easier deformation of the stent. It is inherent with any heating process that cooling occurs after the heating process.

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9. Claims 30 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (5,893,852) in view of Charzewski as applied to Claims 29 and 37 above, and further in view of Humphrey et al. (5,992,000).

Morales/Charzewski teach the invention cited above with the exception of the stent being made of nitinol.

Humphrey et al. teach a stent made of nitinol (col. 9, lines 32-34).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of Morales/Charzewski with a stent made of nitinol, in light of the teachings of Humphrey et al., in order to provide a stent material that is durable.

10. Claims 31, 32, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605).

Morales teaches the invention cited above with the exception of having 8 or 16 dies.

It would have been obvious to one of ordinary skill in the art, at the time of the invention, that the particular number of wedge-shaped dies is clearly a matter of design choice, wherein no significant problems are solved by using either 8 or 16 wedge-shaped dies, versus using 4 or more wedge shaped dies as taught by Morales. It appears that using 4 or more wedge-shaped dies as taught by Morales would work equally as well as using the claimed 8 or 16 wedge-shaped dies.

11. Claims 29 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605) in view of Charzewski (4,942,756).

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Morales teaches the invention cited above with the exception of changing the temperature of the dies or cooling the dies.

Charzewski teaches dies **1a-c** that have a temperature change (col. 4, lines 3-9).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of Morales with dies having a temperature change, in light of the teachings of Charzewski, in order to facilitate easier deformation of the stent. It is inherent with any heating process that cooling occurs after the heating process.

12. Claims 30 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605) in view of Charzewski as applied to Claims 29 and 37 above, and further in view of Humphrey et al. (5,992,000).

Morales/Charzewski teach the invention cited above with the exception of the stent being made of nitinol.

Humphrey et al. teach a stent made of nitinol (col. 9, lines 32-34).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of Morales/Charzewski with a stent made of nitinol, in light of the teachings of Humphrey et al., in order to provide a stent material that is durable.

13. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (5,893,852) in view of Charzewski as applied to Claims 29 and 37 above, and further in view of Langstedt (5,935,476).

Morales/Charzewski teach the invention cited above with the exception of the dies being

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cooled below ambient temperature.

Langstedt teaches dies being cooled below ambient temperature (col. 2, lines 57-65).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of Morales/Charzewski with the dies being cooled below ambient temperature, in light of the teachings of Langstedt, in order to facilitate rapid cooling (col. 1, line 16 of Langstedt).

14. Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales (6,167,605) in view of Charzewski as applied to Claims 29 and 37 above, and further in view of Langstedt (5,935,476).

Morales/Charzewski teach the invention cited above with the exception of the dies being cooled below ambient temperature.

Langstedt teaches dies being cooled below ambient temperature (col. 2, lines 57-65).

It would have been obvious to one of ordinary skill in the art, at the time of the invention, to have provided the invention of Morales/Charzewski with the dies being cooled below ambient temperature, in light of the teachings of Langstedt, in order to facilitate rapid cooling (col. 1, line 16 of Langstedt).

#### Response to Arguments

15. Applicant's arguments filed 5/24/2002 have been fully considered but they are not persuasive.

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16. In response to applicant's argument that Morales (5,893,852) does not teach closely spaced dies, it is noted that 30 (see fig. 2) are clearly closely spaced to each other. Applicant states that the dies are separated by wide gaps relative to the stent, however, the dies have to be closely spaced from each other in order to crimp the stent.

#### Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### Interviews After Final

18. Applicant note that an interview after a final rejection will not be granted unless the intended purpose and content of the interview is presented briefly, in writing (the agenda of the interview must be in writing) to clarify issues for appeal requiring only nominal further

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consideration. <u>Interviews merely to restate arguments of record or to discuss new limitations will</u> be denied. See MPEP 714.13 and 713.09.

### **Contact Information**

19. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, should be directed to the group clerical personnel. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information. M.P.E.P. 203.08. The Group clerical receptionist number is (703) 308-1148.

If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to Tech Center 3700 Customer Service at (703) 306-5648, or fax (703) 872-9301 or by email to <a href="mailto:CustomerService3700@uspto.gov">CustomerService3700@uspto.gov</a>.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc Jimenez whose telephone number is 703-306-5965. The examiner can normally be reached on Monday-Thursday and the second Friday of the biweek, between 9am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Hughes can be reached on 703-308-1806. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Other helpful telephone numbers are listed for applicant's benefit.

Allowed Files & Publication (703) 308-6789 or (888) 786-0101

Assignment Branch (703) 308-9723
Certificates of Correction (703) 305-8309
Drawing Corrections/Draftsman
Petitions/Special Programs (703) 305-9285

Terminal Disclaimers (703) 305-8408

PCT Help Desk (703) 305-3257

If the information desired is not provided above, or a number has been changed, please call the general information help line below.

Information Help line Internet PTO-Home Page 1-800-786-9199 http:www.uspto.gov/

MJ June 19, 2002

I. CUDA-ROSENBAUM PRIMARY EXAMINER

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